

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): LITTRUP, ET AL.

Serial No.: 10/757,768

Filed: 1/14/2004

For: CRYOTHERAPY PROBE

Examiner: VRETTAKOS, PETER J.

Group: 3739

DECLARATION OF ROBERT V. DUNCAN, Ph.D.
SUBMITTED UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22231-1450

Dear Sir/Madam:

I, Robert V. Duncan, PhD hereby declare that:

1. I received a Bachelor of Science Degree in Physics in 1982 from the Massachusetts Institute of Technology (MIT) and my Doctorate in Physics in 1988 from the University of California, Santa Barbara (UCSB).
2. I have 19 years of post-Ph.D. experience in the field of Physics. I am making this oclaration as a consulting physicist paid by CryoDynamics, LLC, in which I hold a business ownership interest. My honors and major professional appointments include:
 - a. Founding Director, New Mexico Consortium's Institute for Advanced Studies at Los Alamos National Lab (2003- date).
 - b. Fellow (and Life Member) of the American Physical Society.
 - c. 2002-2006: Associate Dean for Research, College of Arts and Sciences, University of New Mexico (UNM), on sabbatical leave during the 2004 - 2005 academic year.
 - d. 2001-date: Professor of Physics and Astronomy, UNM.
 - e. 2004 - 2005: Gordon and Betty Moore Distinguished Scholar within the Division of Physics, Mathematics, and Astronomy at Caltech.

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- f. 1988–1996: Physicist at Sandia National Laboratories, promoted to Distinguished Member of Technical Staff in 1995.
- g. 1988 – 1989: Visiting Scientist at the National Bureau of Standards (now the National Institute for Standards and Technology) in Gaithersburg, Maryland.
3. I am the author of over 60 publications in refereed journals and books. Selected publications are referenced in my curriculum vitae, which is attached hereto.
4. I have reviewed the Patent Application for the present case; the first Office Action for this case dated August 25, 2005; the Amendment dated November 23, 2005; the second Office Action dated February 21, 2006; the Amendment dated May 17, 2006; the third Office Action dated September 7, 2006; the Election dated September 18, 2006; a fourth Office Action dated October 18, 2006; the Amendment dated January 10, 2007; and the fifth Office Action dated February 20, 2007. I have also reviewed the Baust et al patent (U.S. Pat. No. 5,520,682) cited in the various office actions.
5. I agree with the statements made in the Amendment dated January 10, 2007. In particular, I agree with the assertion that the term "near a critical point" is a non-ambiguous, definite term to those skilled in the art. There are many references to "near a critical point", "near critical" or "critical region" in the literature. As noted in the Amendment dated January 10, 2007, such examples may be found in, for example, the book entitled "Cryogenic Heat Transfer", by Randall F. Barron. I have reviewed that reference submitted in that amendment. This includes copies of the first page of Chapter 3 (page 97), a portion of page 129, and a portion of page 130 of the reference.
6. I have also reviewed another example of the use of these terms, also submitted in the January 10th Amendment, from the book "Supercritical Fluid Technology in Materials Science and Engineering" by Ya-Ping Sun. This includes page 26 of this reference.
7. I have also reviewed another example of the use of these terms from the book "Supercritical Fluids" by Y. Arai, et al. Specifically, I reviewed copies of a portion of the first page of chapter 3, page 101, and a portion of page 199. These were the portions submitted in the January 10th Amendment. In my opinion all of these references support my strong opinion that the term "near a critical point" is a non-ambiguous, definite term to those skilled in the art. There are many other

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references to this phrase in the literature. I can forward additional references upon the request of the Examiner.

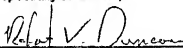
8. The concept is the same in all of these references. When applied to the liquid-vapor critical point, which is the relevant critical point to this invention, the term "near a critical point" refers to the region where the liquid-vapor system is adequately close to the critical point so that the fluctuations of the liquid and vapor phases are large enough to create a large enhancement of the heat capacity over its background value, and there is diminishingly little latent heat of evaporation, since both the distinction of the liquid and vapor phases and the latent heat disappears at the critical point.
9. I have reviewed Claim 20 as amended in the Amendment dated November 23, 2005. I have also reviewed the rejections in the Office Actions of October 18, 2006, January 10, 2007, and February 20, 2007 in which it is stated that my invention is anticipated or rendered obvious by Baust et al. It is my clear professional opinion that what Baust identifies as a "critical point" is physically distinctly different from the critical point of the phase diagram as defined in Claim 20 as amended in the Amendment dated November 23, 2005. That is, Baust et al. are operating at a "critical point of mass flow" - a parameter that is specific and anecdotally-defined based upon the measured performance of each particular cooling device, and not on the well-defined and universal scientific meaning of the critical point in the coolant's phase diagram. The critical point in the phase diagram is specific to the material that is used as the coolant, which in this case is nitrogen. Baust et al. detail the problems of evaporative cooling, and maintaining flow from the boiling of nitrogen and the pressure increases at the liquid-vapor interface. In my opinion, this actually teaches away from the Claim 20 limitation that describes operation in a completely different region of the phase diagram and illustrates the disadvantages of the prior art that are avoided by operating at or near the critical point in the phase diagram of the coolant (in this case nitrogen). No well defined liquid-vapor interface exists physically at this true critical point in the liquid / vapor phase diagram of the coolant (in this case nitrogen) since the distinction of the liquid and vapor phases of the material disappear at the critical point. The 'critical point of mass flow', as discussed within Baust et al., depends on many other properties that are specific to their engineered system, and is not clearly associated with the universally-defined critical point of the liquid / vapor system which is universally defined for the coolant and hence independent of other

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parameters, such as mass flow, in any specific engineered system. I believe that Claim 20 is therefore neither anticipated by nor rendered obvious in view of the Baust reference.

10. I am convinced, based upon my knowledge of extensive performance data in prototypes, that this invention works and that it resolves a long-standing problem that has limited the use of liquid nitrogen in cryogenic tissue ablation devices over the past four decades. Notice that in this invention we do not utilize the latent heat in the liquid / vapor transition of the coolant, as in the prior art. Instead we operate near the liquid / vapor critical point where the distinction between these two phases vanishes, along with the latent heat of cooling. This permits us to flow-cool with near-critical nitrogen while we avoid any possibility of 'vapor lock', since at and above the true critical point there exists no liquid phase.
11. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief and believed to be true, and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,



April 20, 2007

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DATE

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